K123111

LIBRAMEDICAL

JAN 31 2013

5. 510(K) SUMMARY

5.1 ADMINISTRATIVE INFORMATION

5.1.1 Sponsor

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Date Prepared: September 28, 2012

5.1.2 Primary Contact Person

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5.2 DEVICE NAME

Trade Name V8

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Common Name	Balloon Aortic Valvuloplasty Catheter
Classification Name	Catheter, Balloon Aortic Valvuloplasty
Classification	II
Product Code	OZT

5.3 PREDICATE DEVICE

The device is substantially equivalent to the NuMed NuCLEUS-X BAV Catheter (K082776).

5.4 DEVICE DESCRIPTION

The V8 Transluminal BAV Catheter System features an hour-glass shaped dilatation balloon on the distal end of a catheter. The catheter is inserted through a percutaneous entry site into the common femoral artery via an introducer sheath and advanced retrograde to the aortic valve. The catheter is always delivered over a guidewire. The balloon is then inflated to dilate the stenotic aortic valve leaflets in an effort to increase valve opening dimensions and systemic blood flow by improving leaflet mobility. The hour-glass shaped balloon with the undersized waist segment is intended to minimize over-dilatation of the valve annulus while allowing the full dilation of the valve leaflet. The bulbous proximal balloon segment is appropriately sized for the patient's aortic root dimensions to maximize valve leaflet opening.

5.5 INDICATIONS FOR USE/INTENDED USE

The V8 Transluminal BAV Catheter is indicated for Balloon Aortic Valvuloplasty.

The V8 and predicate device are indicated for balloon aortic valvuloplasty for both a palliative treatment as well as to predilate the annulus prior to transcatheter aortic valve replacement surgery. There are no differences in indications and therefore do not raise any new questions about the safety and effectiveness of the device.

5.6 TECHNOLOGICAL CHARACTERISTICS

The V8 balloon has an hour glass shape at low and at rated burst pressures. The V8 balloon is intended to provide a means for dilation of stenotic aortic valve leaflets while minimizing dilation of the aortic annulus by virtue of its hour-glass shape. The V8 balloon is made of clear non-compliant polymeric material. The balloon will be available in four diameter sizes (22mm – 28mm). The waist of the hour glass balloon is sized such that it is smaller than the bulb diameter up to the rated burst pressure.

The catheter will be available in standard working lengths (107cm – 113cm) and is compatible with a 12F or 14F introducer sheath. It is introduced through the femoral artery via the introducer sheath and tracked over a 0.035" wire. The catheter's inner shaft beneath the balloon is marked with radiopaque platinum iridium marker bands, one at the center of the waist, and one each at the outside edges of the proximal and distal balloon shoulders. The catheter is packaged in a heat sealed Tyvek pouch and provided sterilized. It is intended for single use only. These characteristics are comparable with the predicate device.

The predicate device also has an hour-glass shape at low pressures. However, it loses its shape at the working pressure and the rated burst pressure. In contrast, the V8 balloon's hour-glass shape is retained even at rated burst pressure. However, this difference in the balloon shape does not raise new or different questions of safety and effectiveness. The effectiveness of the device is determined by the bulbous section of the balloon and this is similar in diameter to the predicate device. The waist of the V8 balloon reduces the probability of annular distention and hence the risk of dissection. Hence, no new questions of safety are raised.

The shaft of the V8 catheter is similar in construction to that of the predicate device. Both device shafts are dual lumen with each lumen terminating in a female luer at the proximal hub.

5.7 PERFORMANCE DATA

The V8 Transluminal BAV Catheter System is tested and meets all its physical and performance specifications including:

- Balloon rated burst pressure
- Balloon compliance
- Critical dimension verifications
- Guidewire and introducer compatibility
- Fluoroscopic visualization
- Deflation times
- Repeat inflation
- Leak
- Tensile
- Kink
- Torque
- Luer lock compatibility
- Distribution

In addition, the device was tested for biocompatibility per ISO 10993-1 for short duration contact with blood (<24 hours). The device is sterilized by ethylene oxide to an SAL 10^{-6} level. These performances are similar to that described by the predicate device.

The preclinical testing showed that the device meets specifications before and after aging indicating that the device is as safe and effective as the predicate device.

5.8 SUBSTANTIAL EQUIVALENCE

The V8 BAV Catheter System is substantially equivalent to the NuMed NuCLEUS-X BAV Catheter (K082776). They have similar intended use, and treat a similar target population. Both devices are over-the-wire catheters with coaxial lumen. Both devices employ an hour-glass shaped balloon with radiopaque markings. The predicate device, however, does not hold the hour-glass shape at the working pressure. In contrast, the V8 balloon's hour-glass shape is retained even at rated burst pressure. This difference in the balloon shape does not raise new or different questions of safety and effectiveness. Both devices are compatible with the 0.035" wire

and have the similar principles of operation. Both devices are biocompatible and meet ISO 10993-1, and both were sterilized with ethylene oxide with a sterility assurance of 10^{-6}.

5.9 CONCLUSION

The V8 and the predicate NuCLEUS-X catheters have similar intended use and technological characteristics. The noted differences in balloon waist diameter do not raise new or different questions of safety and effectiveness. Therefore, the V8 Transluminal BAV Catheter System and predicate are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

JAN 31 2013

Intervalve, Inc..
c/o Libra Medical Inc.
8401 73rd Avenue North, Suite 63
Minneapolis, MN 55428
ATTN: Ms. Julie Bodmer

Re: K123111
Trade/Device Name: Intervalve V8 transluminal BAV Catheter
Regulation Number: 21 CFR 870.1255
Regulation Name: Ballon Aortic Valvuloplasty Catheter
Regulatory Class: Class II (two)
Product Code: OZT
Dated: September 28, 2012
Received: October 3, 2012

Dear Ms. Bodmer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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4. INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): K123111

Device Name: V8 Transluminal BAV Catheter

Indications for Use:
The V8 Transluminal BAV Catheter is indicated for Balloon Aortic Valvuloplasty.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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